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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,316	04/12/2005	David B Mount, Jr.	1242/50/3 PCT/US	2379

25297 7590 10/09/2007

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EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	**PAPER NUMBER**
1646	

MAIL DATE	DELIVERY MODE
10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,316	MOUNT, JR. ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-69* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, drawn to SLC26A7 polypeptide.

Group II, claim(s) 6, drawn to a system for recombinant expression of SLC26A7 polypeptide.

Group III, claim(s) 7-10, drawn to isolated SLC26A7 nucleic acid.

Group IV, claim(s) 11, drawn to a method for detecting a SLC26A7 nucleic acid.

Group V, claim(s) 12-14, drawn to a method for producing an antibody that specifically recognizes a SC26A7 polypeptide.

Group VI, claim(s) 15, drawn to an antibody produced by the method of claim 12.

Group VII, claim(s) 16, drawn to a method for detecting a level of a SLC26A7 polypeptide.

Group VIII, claim(s) 17-21, drawn to a method for detecting a modulator of SLC26A7 polypeptide by assaying a level or quality of SLC26A7 function using a recombinant expression system.

Group IX, claim(s) 22, drawn to an anion modulator identified by the method of claim 17.

Group X, claim(s) 23-25, drawn to a method for modulating anion transport activity in a subject using the modulator of claim 17.

Group XI, claim(s) 26-30, drawn to a method for identifying an anion exchanger modulator by assaying binding of a test substance to the SLC26A7 polypeptide.

Group XII, claim(s) 31, drawn to an anion modulator identified by the method of claim 26.

Group XIII, claim(s) 32-34, drawn to a method for modulating anion transport activity in a subject using the modulator of claim 26

Group XIV, claim(s) 35-40, drawn to SLC26A9 polypeptide.

Group XV, claim(s) 41 drawn to a system for recombinant expression of SLC26A9 polypeptide.

Group XVI, claim(s) 42-45, drawn to isolated SLC26A9 nucleic acid.

Group XVII, claim(s) 46, drawn to a method for detecting a SLC26A9 nucleic acid.

Group XVIII, claim(s) 47-49, drawn to a method for producing an antibody that specifically recognizes a SC26A9 polypeptide.

Group XIX, claim(s) 50, drawn to an antibody produced by the method of claim 47.

Group XX, claim(s) 51, drawn to a method for detecting a level of a SLC26A9 polypeptide.

Group XXI, claim(s) 52-56, drawn to a method for detecting a modulator of SLC26A9 polypeptide by assaying a level or quality of SLC26A9 function using a recombinant expression system.

Group XXII, claim(s) 57, drawn to an anion modulator identified by the method of claim 52.

Group XXIII, claim(s) 58-60, drawn to a method for modulating anion transport activity in a subject using the modulator of claim 52.

Group XXIV, claim(s)61-65, drawn to a method for identifying an anion exchanger modulator by assaying binding of a test substance to the SLC26A9 polypeptide.

Group XXV, claim(s) 66, drawn to an anion modulator identified by the method of claim 64.

Group XXVI, claim(s) 68-69, drawn to a method for modulating anion transport activity in a subject using the modulator of claim 56

The inventions listed as Groups I-XXVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The unifying technical feature of invention I is the SLC26A7 polypeptide. The specification discloses a SLC26A7 polypeptide can comprise a polypeptide substantially identical to SEQ ID NO:2 or 4 (see page 5, lines 11-15). The term "substantially", is used in the specification to describe a level of similarity that must be contained in polypeptide for it to be considered a SLC26 polypeptide. A protein is substantially identical to a SLC26 protein, when it is at least about 35% identical to any of even-numbered SEQ ID NOs:2-10 (see page 24, lines 1-10). Further page 16 of the specification discloses that the terms "SCC26 and terms including SCC26 (e.g. SCLC26A7 and SCLC26A9) are used herein to refer to nucleic acids that encode a SCLC26 polypeptide (see page 16, lines 18-25). Priority document, WO200194583 (LEXICON GENETICS INC.) discloses a polypeptide that has 89.7% query match and 87.7% best local similarity to SEQ ID NO:2 (SCL26A7) of instant application, see sequence comparison below. The polypeptide disclosed by LEXICON GENETICS INC is considered to be a SCLC26A7 polypeptide based on the definition in the specification. Because the special technical feature of the invention has been found in the prior art, a technical relationship does not exist between the claimed groups. Therefore, unity of invention is lacking.

The inventions are drawn to patentably distinct methods and patentably distinct compounds. The compounds claimed having materially different structures and functions. The methods are patentably distinct because they achieve different goals, using different method steps and compounds. Accordingly unity is lacking.

GenCore version 5.1.9
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OM protein - protein search, using sw model

Run on: August 26, 2006, 01:41:55 ; Search time 149 Seconds

(without alignments)
2012.980 Million cell
updates/sec

Title: PCT-US03-06220-2
Perfect score: 3328
Sequence: 1 MTGAKRKKRSVLWGKMHTPH.....AITIIQSNKNLSKASDHSEV 656

Scoring table: BLOSUM62
Gapop 10.0 , Gapext 0.5

Searched: 2589679 seqs, 457216429 residues

Total number of hits satisfying chosen parameters: 2589679

Minimum DB seq length: 0
Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%
Maximum Match 100%
Listing first 45 summaries

Database : A_Geneseq_8:*
1: geneseqp1980s:*
2: geneseqp1990s:*
3: geneseqp2000s:*
4: geneseqp2001s:*
5: geneseqp2002s:*
6: geneseqp2003as:*
7: geneseqp2003bs:*
8: geneseqp2004s:*
9: geneseqp2005s:*
10: geneseqp2006s:*

RESULT 3
AAU74916
ID AAU74916 standard; protein; 656 AA.
XX
AC AAU74916;
XX
DT 23-APR-2002 (first entry)
XX
DE Novel human protein (NHP) sequence #5.
XX
KW Novel human protein; NHP; transporter protein; polymorphism;
KW mental disorder; biological disease; medical disorder.
XX
OS Homo sapiens.
XX
FH Key Location/Qualifiers
FT Misc-difference 485
FT /note= "Encoded by GWA"
XX
PN WO200194583-A2.

XX
PD 13-DEC-2001.
XX
PF 06-JUN-2001; 2001WO-US018393.
XX
PR 07-JUN-2000; 2000US-0210045P.
XX
PA (LEXI-) LEXICON GENETICS INC.
XX
PI Walke DW, Scoville J;
XX
DR WPI; 2002-147673/19.
DR N-PSDB; ABK12980.
XX
PT New human polynucleotides encoding proteins that share sequence
PT similarity with mammalian transporter proteins, useful for determining
PT genomic structures, identifying polymorphisms, or as reagents for
PT diagnosis or drug screening.
XX
PS Claim 1; Page 44-45; 48pp; English.
XX
CC The present invention relates to new isolated nucleic acid molecules
CC comprising a nucleotide sequence encoding a protein that shares sequence
CC similarity with mammalian transporter proteins. The invention also
CC relates to a nucleotide sequence that hybridises under stringent
CC conditions to the nucleotide sequence comprising 1971 bp (ABK12980) fully
CC defined in the specification or its complement. The isolated nucleic acid
CC and the protein it encodes are useful for identifying a coding sequence
CC and mapping a unique gene to a particular chromosome, identifying and
CC characterising the temporal and tissue specific expression of a gene,
CC screening a human genomic library, determining the genomic structure of a
CC given locus/allele or designing diagnostic tests. The nucleic acids and
CC proteins are particularly useful for identifying polymorphisms and in
CC amplification assays to detect mutations within the exons, introns and
CC splice sites that can be used in diagnostics and pharmacogenomics. These
CC are also useful for generating antibodies, as reagents in diagnostic
CC assays or for identifying other cellular gene products related to novel
CC human proteins. The nucleotides can be used as reagents in assays for
CC screening for compounds that can be employed as pharmaceutical reagents
CC useful in the therapeutic treatment of mental, biological or medical
CC disorders and diseases. The present amino acid sequence represents novel
CC human protein #5 that is one of several (AAU74912- AAU74917) novel human
CC proteins (NHP) of the invention
XX
SQ Sequence 656 AA;

Query Match 89.7%; Score 2984; DB 5; Length 656;
Best Local Similarity 87.7%; Pred. No. 1.5e-304;
Matches 575; Conservative 44; Mismatches 37; Indels 0; Gaps 0;

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Qy          1 MTGAKRKKRSVLWGKMHTPHREDIKQWCKRRLPILEWAPQYNLKENLLPDTVSGIMLAVQ 60
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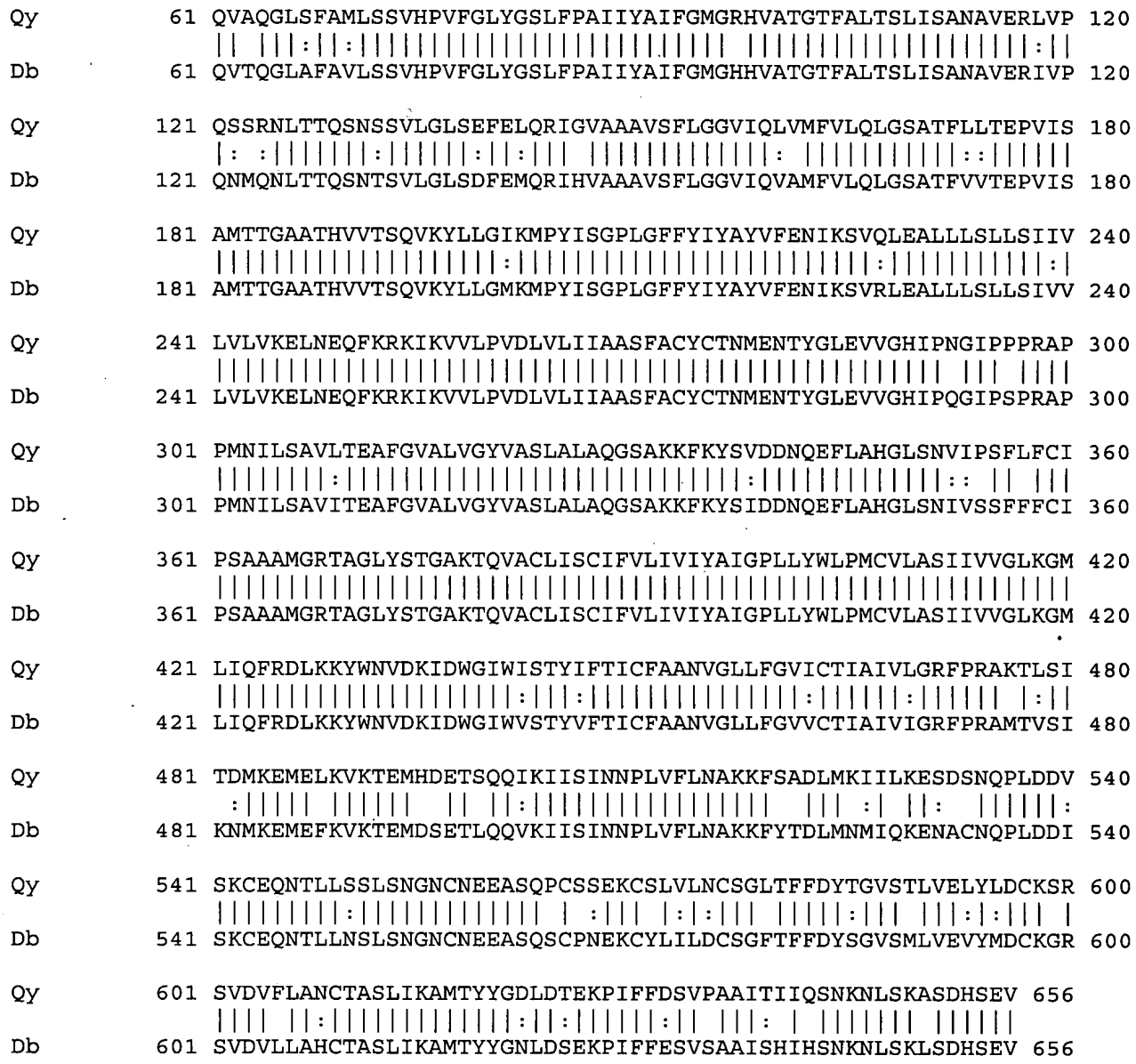

Additional elections.

2. The claims of Group I-XIII are drawn to a multitude of nucleic acids, SEQ ID NOs: 1, 3 encoding the polypeptides of SEQ ID NO:2, 4, respectively, and methods which use said nucleic acids, or use of their encoded polypeptides, antibodies that bind

said polypeptide and cells containing said polypeptides. The claims apply to numerous structurally and functionally different nucleic acids/polypeptides/antibodies. This constitutes recitation of an implied, mis-joined Markush group that contains multiple, independent and distinct inventions. Each of the different nucleic acids/polypeptides/antibodies/and methods of use are independent and distinct because no common structural or functional properties are shared. There is no description of definitive structural or functional features of the claimed Markush group. The Markush group contains no conserved regions which is critical to the structure and function of the genus claimed. The common function of the claimed genus of polynucleotides, which is based upon a common property or critical technical feature of the genus claimed is not disclosed. Accordingly, these claims are subject to restriction because they do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for reasons given above. **Upon election of Groups I-XII, Applicants is additionally required to elect a single nucleic acid encoding its respective protein. This requirement is not to be constructed as a requirement for election of species, since each of the compounds recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.**

3. The claims of Group XIV-XVI are drawn to a multitude of nucleic acids, SEQ ID NOs: 5, 7 and 9 encoding the polypeptides of SEQ ID NO:6, 8 and 10, respectively, and methods which use said nucleic acids, or use of their encoded polypeptides,

antibodies that bind said polypeptide and cells containing said polypeptides. The claims apply to numerous structurally and functionally different nucleic acids/polypeptides/antibodies. This constitutes recitation of an implied, mis-joined Markush group that contains multiple, independent and distinct inventions. Each of the different nucleic acids/polypeptides/antibodies/and methods of use are independent and distinct because no common structural or functional properties are shared. There is no description of definitive structural or functional features of the claimed Markush group. The Markush group contains no conserved regions which is critical to the structure and function of the genus claimed. The common function of the claimed genus of polynucleotides, which is based upon a common property or critical technical feature of the genus claimed is not disclosed. Accordingly, these claims are subject to restriction because they do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for reasons given above. **Upon election of Groups XIV-XVI, Applicants is additionally required to elect a single nucleic acid encoding its respective protein. This requirement is not to be constructed as a requirement for election of species, since each of the compounds recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.**

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143) and identification of the claims encompassing the elected

invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final

rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Advisory

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NSB

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